IN THE UNITED STATES DISTRICT COURT
FORT THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, et al., *ex rel*.	)	
Plaintiffs,	)	
JAMIE SIEGEL M.D.,	)	
Plaintiff-Relator,	)	Case No. CIV-15-00114-PRW
v.	)	
NOVO NORDISK, INC.,	)	
Defendant.	)	

ORDER

Before the Court is Defendant's Motion to Dismiss the Second Consolidated Complaint (Dkt. 124) and Motion to Dismiss the Second Consolidated Complaint in Part Pursuant to Anti-SLAPP Statutes (Dkt. 127). For the reasons explained below, the Motion to Dismiss the Second Consolidated Complaint (Dkt. 124) is **GRANTED IN PART** and **DENIED IN PART**, and the Motion to Dismiss the Second Consolidated Complaint in Part Pursuant to Anti-SLAPP Statutes (Dkt. 127) is **DENIED AS MOOT**.

Background[1]

This case arises from alleged violations of the False Claims Act ("FCA") by Defendant Novo Nordisk, Inc., a global healthcare company that specializes in diabetes

[1] At this stage, the Court accepts Plaintiffs' well-pleaded allegations as true. Therefore, the account presented in this factual background reflects Plaintiffs' account.

care, hemophilia care, growth hormone therapy, and hormone replacement therapy. The Plaintiff-Relator, Dr. Jamie Siegel, worked at Novo Nordisk from 2008 to 2009 as a Director of Hematology in Clinical Development, Medical, and Regulatory Affairs. The questions presented by the motions are whether the Second Consolidated Complaint satisfies Federal Rule of Civil Procedure 9(b)'s heightened pleading standard for fraud-based claims and whether the claims fail as a matter of law.

During her time at Novo Nordisk, part of Dr. Siegel's duties included assisting Novo Nordisk in marketing its drug NovoSeven. NovoSeven is used to treat persons with hemophilia, a rare, life-threatening, genetic bleeding disorder in which blood does not clot normally. Persons with hemophilia bleed longer than others after an injury because they lack proteins in the blood called clotting "factors" required for normal blood clotting. Although in the 1980s pharmaceutical companies developed methods to manufacture factors, approximately 15–20% of persons with hemophilia develop an antibody to their deficient or missing factors. This antibody prevents blood from clotting, so persons with the antibody often need a special product called a "bypassing agent" to stop bleeds. NovoSeven is a bypassing agent approved by the Food and Drug Administration ("FDA") to treat acute bleeding and prevent excessive bleeding during surgeries. NovoSeven's package insert also directs injections of the drug at a dosage of 90µg/kg every two hours until bleeding stops. Importantly for Plaintiffs' claims, the FDA has not approved NovoSeven for doses higher than 90µg/kg, nor has it approved NovoSeven for routine, prophylactic use for preventing spontaneous bleeds from occurring in the first place. Because they are not approved by the FDA, such uses would be considered "off-label."

Dr. Siegel brings the Second Consolidated Complaint against Novo Nordisk *qui tam* on behalf of the United States, twenty-nine states, the District of Columbia, and the City of Chicago, with the State of Washington intervening with respect to Dr. Siegel's claims brought on behalf of Washington. Plaintiffs allege that Novo Nordisk illegally marketed NovoSeven for off-label uses—phrophylaxis and dosing regimens above the FDA-approved amount—and provided illegal kickbacks to physicians and patients. Ultimately, Plaintiffs argue, the alleged off-label marketing and kickbacks resulted in false claims being filed with the government in violation of the FCA and various state laws.

Legal Standard

When reviewing a Rule 12(b)(6) motion to dismiss, all well-pleaded allegations in the complaint must be accepted as true and viewed "in the light most favorable to the plaintiff."[2] Parties bear the "obligation to provide the grounds of [their] entitle[ment] to relief," which requires "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."[3] The pleaded facts must be sufficient to establish that the claim is plausible.[4] In considering whether a claim is plausible, the Court "liberally construe[s] the pleadings and make[s] all reasonable inferences in favor of the non-moving party."[5] Generally, a complaint will survive a Rule 12(b)(6) motion to dismiss if it "state[s]

[2] *Alvarado v. KOB-TV, L.L.C.*, 493 F.3d 1210, 1215 (10th Cir. 2007) (quoting *David v. City & County of Denver*, 101 F.3d 1344, 1352 (10th Cir. 1996)).

[3] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks and citations omitted) (alteration in original).

[4] *See id.*

[5] *Brokers' Choice of Am., Inc. v. NBC Univ., Inc.*, 861 F.3d 1081, 1105 (10th Cir. 2017).

a claim to relief that is plausible on its face," meaning that it pleads sufficient facts to support a "reasonable inference that the defendant is liable for the misconduct alleged."[6] But fraud-based claims, like those under the False Claims Act, must satisfy Rule 9(b)'s heightened pleading standard.[7]

Rule 9(b) requires that "a party must state with particularity the circumstances constituting fraud. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."[8] The purpose of Rule 9(b) is "to afford defendant[s] fair notice of plaintiff[s'] claims and the factual ground upon which [they] are based."[9] FCA claims satisfy Rule 9(b)'s requirements when they "provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims."[10] For most FCA claims it is necessary to allege "actual submissions of a specific request for payment to the government," but it is unnecessary to allege such specific requests for payment when the

[6] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

[7] *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2004 n.6 (2016) ("False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) . . . .").

[8] Fed. R. Civ. P. 9(b).

[9] *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 (10th Cir. 2018) (citing *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)).

[10] *Id.*

complaint demonstrates the "specifics of a fraudulent scheme and provide[s] an adequate basis for a reasonable inference that false claims were submitted as part of that scheme."[11]

Discussion

In its motion to dismiss, Novo Nordisk argues that Counts One through Thirty-Five in the Second Consolidated Complaint fail to satisfy Rule 9(b)'s pleading requirements and fail to state a claim as a matter of law under Rule 12(b)(6). Specifically, Novo Nordisk maintains (1) that Plaintiffs failed to link the allegations of the underlying schemes—off-label marketing and illegal kickbacks—with any claims presented to United States or state governments and (2) that off-label marketing and kickbacks do not render a claim "false or fraudulent" under the FCA or state law. Novo Nordisk also argues that, even if any of Plaintiffs' claims meet the requirements of Rules 9(b) and 12(b)(6), these claims should be dismissed to the extent they are time-barred or narrowed based on state-law requirements. In the alternative, Novo Nordisk maintains that Plaintiffs' claims violate the First Amendment and numerous states' "Anti-SLAPP" laws. For the reasons explained below, the Court agrees that Counts Three through Thirty and Counts Thirty-Three through Thirty-Five do not satisfy Rule 9(b)'s pleading requirements but disagrees with respect to Counts One, Two, Thirty-One, and Thirty-Two. The Court also finds that Plaintiffs' claims under Counts One, Two, Thirty-One, and Thirty-Two do not fail as a matter of law.

A. Rule 9(b)

[11] *United States ex rel. Wagner v. Care Plus Home Health Care, Inc.*, No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *4 (N.D. Okla. Dec. 11, 2017) (citing *Lemmon*, 614 F.3d at 1172).

Novo Nordisk argues that Counts One through Thirty-Five in the Second Consolidated must be dismissed for failure to satisfy Rule 9(b)'s pleading requirements. For the reasons that follow, the Court concludes that Plaintiffs have satisfied Rule 9(b)'s pleading requirements for Counts One, Two, Thirty-One, and Thirty-Two based on alleged violations of the FCA and Washington law. Plaintiffs have not, however, pleaded with sufficient particularity Counts Three through Thirty and Counts Thirty-Three through Thirty-Five.

1. False Claims Act (Counts One and Two)

"The False Claims Act covers all fraudulent attempts to cause the government to pay out sums of money."[12] It does so by permitting recovery of civil penalties and treble damages from, among others,[13] anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[14]

The Act has two enforcement mechanisms, one public and one private. "'First, the Government itself may' sue 'the alleged false claimant' to remedy the fraud."[15] "Second, 'a private person (the relator) may bring a qui tam' suit on behalf of the government and

[12] *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 755 (10th Cir. 2019) (cleaned up).

[13] 31 U.S.C. § 3729(a)(1)(C)–(G).

[14] *See id.* § 3729(a)(1)(A) & (B).

[15] *KeyPoint*, 923 F.3d at 736 (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000)).

also for herself alleging that a third party made fraudulent claims for payment to the government."[16] "'As a bounty for identifying and prosecuting fraud,' relators get to keep a portion 'of any recovery they obtain.'"[17] The FCA is not, however, "an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[18] "FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the [Federal Drug and Cosmetic Act], that are independent of any false claim."[19]

There are two varieties of FCA claims: factually false claims and legally false claims.[20] "Factually false claims generally require a showing that the payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."[21] Legally false claims, on the other hand, "generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment."[22] Furthermore, legally false claims can rest upon one

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[16] *Id.* (quoting *Vt. Agency of Nat. Res.*, 529 U.S. at 769).

[17] *Id.* (quoting *United States ex rel. Boothe v. Sun Healthcare Grp., Inc.*, 496 F.3d 1169, 1172 (10th Cir. 2007) (citing 31 U.S.C. § 3730(d))).

[18] *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016) (internal quotation marks and citation omitted).

[19] *United States ex rel. Gardner v. Vanda Pharms., Inc.*, 554 F. Supp. 3d 146, 157 (D.D.C. 2021).

[20] *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018).

[21] *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1168 (10th Cir. 2016) (quotation omitted).

[22] *Id.*

of two theories: express false certification or implied false certification.[23] A claim is based upon an express-false-certification theory when the complaint alleges that "a government payee falsely certifie[d] compliance with a particular statute, regulation or contractual term, where compliance [was] a prerequisite to payment."[24] Conversely, an implied-false-certification claim does not require a false representation; instead, "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."[25]

In Count One of the Second Consolidated Complaint, Plaintiffs allege that Novo Nordisk "knowingly present[ed], or caus[ed] to be presented, a false or fraudulent claim for payment or approval" in violation of § 3729(a)(1)(A).[26] And in Count Two, Plaintiffs allege that Novo Nordisk "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of § 3729(a)(1)(B).[27] While claims under § 3729(a)(1)(A) may be based upon either an express-false-certification theory or an implied-false-certification theory, claims under §

[23] *Polukoff*, 895 F.3d at 741.

[24] *Id.*

[25] *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 181 (2016).

[26] *See* 31 U.S.C. § 3729(a)(1)(A).

[27] *See id.* § 3729(a)(1)(B).

3729(a)(1)(B) may only be based upon factually false claims (not alleged here) and express-false-certification claims.[28] The Court will first address Plaintiffs' § 3729(a)(1)(A) claim as alleged in Count One before turning to their § 3729(a)(1)(B) claim as alleged in Count Two.

a. Count One

Claims brought under § 3729(a)(1)(A) require plaintiffs to show falsity, materiality, and knowledge.[29] Furthermore, plaintiffs must plead with particularity the underlying schemes that allegedly resulted in false claims.[30] Therefore, to survive a motion to dismiss, it is insufficient to simply plead the underlying scheme; rather, "the complaint must provide enough information to describe a fraudulent scheme to support a plausible inference that false claims were submitted."[31]

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[28] *Lemmon*, 614 F.3d at 1168; *United States ex rel. Wagner v. Care Plus Home Health Care, Inc.*, No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *6 (N.D. Okla. Dec. 11, 2017) ("In contrast to 31 U.S.C. § 3729(a)(1)(A), only factually false claims and express false certification [claims] are actionable under 31 U.S.C. § 3729(a)(1)(B).").

[29] *See Lemmon*, 614 F.3d at 1168; *Wagner*, 2017 WL 6329850, at *6. The parties discuss the falsity requirement in relation to Rule 12(b)(6), so the Court addresses the argument in that section. With respect to materiality, Novo Nordisk fails to fully develop any argument on this requirement, *see* Pls.' Resp. (Dkt 145), at 22, Def.'s Reply (Dkt. 155), at 4, so the Court does not address it. And Rule 9(b) allows knowledge to be alleged generally, so at this stage Plaintiffs are not required to meet a higher pleading standard to demonstrate the knowledge requirement for their FCA claims.

[30] *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 203 L. Ed. 2d 791 (2019).

[31] *Lemmon*, 614 F.3d at 1173.

Off-Label Promotion: Plaintiffs' allegations meet Rule 9(b)'s heightened pleading standard with respect to the underlying off-label promotion scheme. Plaintiffs describe in significant detail Novo Nordisk's alleged off-label marketing of NovoSeven. Indeed, most of the Second Consolidated Complaint's 135 pages discuss the particulars of how Novo Nordisk promoted NovoSeven for uses that were not approved by the FDA—prophylaxis and doses higher than 90µg/kg. For example, Plaintiffs state that Novo Nordisk incentivized sales representatives based on sales for off-label uses;[32] disseminated posters promoting off-label uses;[33] publicized studies showing the efficacy of off-label uses;[34] and paid physicians to give promotional lectures in favor of off-label uses to fellow practitioners.[35] For one patient in particular—"Patient A"—the Second Consolidated Complaint alleges that Novo Nordisk sent a representative to the patient's facility to promote NovoSeven for prophylaxis.[36] The Court thus finds that Plaintiffs have pleaded the underlying off-label-promotion scheme with particularity sufficient to satisfy Rule 9(b)'s heightened pleading standard.

Kickbacks: Plaintiffs have also pleaded with particularity Novo Nordisk's alleged underlying kickback scheme. Specifically, Plaintiffs claim that Novo Nordisk's alleged

[32] Pls.' SCC ¶ 16.

[33] *Id.* ¶¶ 217, 177.

[34] *Id.* ¶¶ 11–12, 170–71, 174–85, 194.

[35] *Id.* ¶¶ 20, 191–93.

[36] *Id.* ¶¶ 107–08.

kickbacks violated the Anti-Kickback Statute[37] ("AKS") and the Beneficiary Inducements Statute[38] ("BIS"), which resulted in false claims being filed in violation of the FCA.

The AKS criminalizes, in relevant part, the "knowing[ ] and willful[ ]" offer or payment of "any remuneration (including any kickback, bribe, or rebate)" to induce a person to "recommend . . . ordering any . . . service . . . for which payment may be made in whole or in part under a [f]ederal health care program."[39] A person violates the AKS so long as *one purpose* of the offer or payment is to "induce or reward the referral or recommendation of business . . . to a program under which payments may be made from federal funds."[40] In 2010, Congress amended the AKS to provide an express link to the FCA: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes [of the FCA]."[41] So long as Plaintiffs "plead with particularity that [Novo Nordisk] made kickbacks with the intent of inducing referrals, and plead 'particular details of a scheme . . . paired with reliable indicia that lead

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[37] 42 U.S.C. § 1320a-7b(b). The AKS does not apply to claims submitted to the Federal Employees Health Benefits Program ("FEHBP"), which is covered by 5 U.S.C. § 8901 *et seq*. Therefore, as Plaintiffs explain, their claims as to FEHBP are limited to those predicated on Novo Nordisk's alleged promotion of non-reimbursable, off-label uses of NovoSeven.

[38] *Id.* § 1320a-7a(a)(5).

[39] *Id.* § 1320a-7b(b)(2)(B).

[40] *See Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019); *see also United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.").

[41] 42 U.S.C. § 1320a-7b(g), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 1110148, 124 Stat. 119 (2010).

to a strong inference that claims were actually submitted,' the separate elements of the AKS and FCA are satisfied."[42]

Plaintiffs have sufficiently pleaded the separate elements of the AKS and FCA. They allege that Novo Nordisk employees "plied [Patient A] and his guardian with money and in-kind donations including tutoring lessons, travel and meal expenses, computer programming, a computer and a wheelchair" to induce him to use the drug NovoSeven.[43] Plaintiffs also allege that Novo Nordisk paid kickbacks to physicians for participating in studies, writing manuscripts, serving on internal Novo Nordisk advisory boards, speaking at patient events, and otherwise using their influence to promote off-label uses of NovoSeven.[44] These allegations are supported with numerous details, including names, dates, and amounts.[45] As with Plaintiffs' assertions related to the alleged off-label marketing scheme, the Court concludes they have sufficiently pleaded the underlying alleged kickback scheme.

Novo Nordisk argues, however, that since Plaintiffs' claims allegedly arose before the 2010 AKS amendment, any alleged AKS violations before 2010 did not render resulting claims false. Novo Nordisk claims that "the AKS was amended to provide that claims submitted in violation of the AKS are false or fraudulent for purposes of the FCA"

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[42] *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013), *aff'd sub nom. U.S. ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (citing *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

[43] Pls.' SCC ¶¶ 20, 21, 23, 107, 108, 117.

[44] *Id.* ¶¶ 20–22, 25–26, 107–08, 110–28, 186–96.

[45] *Id.*

and that "[f]or claims before 2010, Relator has failed to plead any express or implied certification of compliance rendered false due to [Novo Nordisk's] alleged AKS violation, and therefore has not alleged a basis for falsity."[46] But "[a]lthough the [AKS] amendment is not retroactive, plaintiffs may still bring a False Claims Act case for claims submitted before 2010, as the amendment clarified, but did not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act."[47] The Court thus rejects Novo Nordisk's argument related to pre-2010 claims for reimbursement.

Plaintiffs also assert that claims were rendered false as a result of Novo Nordisk's alleged violations of the BIS. The BIS makes it a violation to offer remuneration to a Medicare or Medicaid patient that "is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid]."[48] Remuneration "includes . . . transfers of items or services for free or for other than fair market value," subject to certain exceptions.[49] While the BIS does not apply to some drug manufacturers that provide remuneration to Medicare or Medicaid beneficiaries on the rationale that a drug manufacturer is not ordinarily a "particular provider, practitioner, or supplier," it does apply to drug manufacturers that "also own or operate, directly or indirectly, pharmacies,

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[46] Def.'s Mem. (Dkt. 125), at 17.

[47] *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018) (cleaned up) (citing *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 439 (3d Cir. 2004)).

[48] 42 U.S.C. § 1320a-7a(a)(5).

[49] *Id.* § 1320a-7a(i)(6).

pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs."[50] Recognizing this distinction, Plaintiffs have pleaded with particularity that Novo Nordisk "operate[d], directly or indirectly," a pharmacy (RxCrossroads) that submitted claims to Medicare and Medicaid that were allegedly tainted with kickbacks.[51] For example, Plaintiffs allege that Novo Nordisk—rather than RxCrossroads—decided on a patient-by-patient basis "what gifts and benefits patients would receive" from RxCrossroads and directed RxCrossroads to provide remuneration to Medicare and Medicaid patients, including pre-paid credit cards, travel, lodging, computers, and software.[52] The Court thus rejects, at the motion-to-dismiss stage, Novo Nordisk's argument that it is not subject to the BIS.

Plaintiffs have also sufficiently described the underlying off-label promotion and kickback schemes to support a plausible inference that false claims were submitted. Novo Nordisk argues that Plaintiffs have failed to provide any details of actual claims submitted, as required under *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*.[53] But Novo Nordisk's Memorandum in Support of its Motion to Dismiss omits more recent Tenth

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[50] *See Pfizer, Inc v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67, 78 (2d Cir. 2022) (citing OIG, Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2022), https://oig.hhs.gov/fraud/docs/alertsAndbulletins/SABGiftsandInducements.pdf).

[51] Pls.' SCC ¶¶ 21–23, 112–13, 117–21, 127.

[52] *Id.* ¶¶ 114–15, 117–22.

[53] *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 728 (10th Cir. 2006), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 203 L. Ed. 2d 791, 139 S. Ct. 1507 (2019).

Circuit precedent, *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, which states that "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme."[54] Thus, "[p]ractically speaking, FCA claims comply with Rule 9(b) when they 'provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims."[55] And when a complaint demonstrates the "specifics of a fraudulent scheme and provide[s] an adequate basis for a reasonable inference that false claims were submitted as part of that scheme[,] . . . allegations of the actual submission of a specific request for payment to the government . . . may not be necessary."[56]

With respect to their counts brought under the FCA, Plaintiffs have adequately pleaded the who, what, when, where, and how of the alleged claims. For example, as previously discussed, Plaintiffs allege that Novo Nordisk visited Patient A's medical facility to promote off-label uses of NovoSeven and that Patient A used NovoSeven for prophylaxis and doses above the FDA-approved amount, as well as that NovoNordisk provided kickbacks to Patient A to induce him to use NovoSeven. Plaintiffs have thus linked the alleged off-label promotion and kickback scheme to claims submitted on behalf of a specific patient (Patient A) whose claims resulted in payments from the State of

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[54] *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010).

[55] *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 (10th Cir. 2018) (citing *Lemmon*, 614 F.3d at 1172).

[56] *United States ex rel. Wagner v. Care Plus Home Health Care, Inc.*, No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *4 (N.D. Okla. Dec. 11, 2017) (citing *Lemmon*, 614 F.3d at 1172).

Washington[57] totaling a specific sum ($53,042,060.19) over a specific duration (2009–2013). These allegations are sufficient "to afford [Novo Nordisk] fair notice of [Plaintiffs'] claims and the factual ground upon which [they] are based" and "provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme."[58]

Novo Nordisk argues, however, that Plaintiffs "fail[] to allege with particularity 'how' [Novo Nordisk's] alleged fraud *caused* the submission of false claims."[59] It continues that "Relator does not allege that [Novo Nordisk] itself submitted any reimbursement claims or participated in the claims submission process. Rather, she posits a convoluted causal chain in which [Novo Nordisk's] off-label promotion persuaded physicians to write lawful off-label prescriptions, and then the independent third parties over whom [Novo Nordisk] has no control submitted reimbursement claims."[60] Novo Nordisk asserts that this causal chain cannot satisfy the FCA's causation requirement "[a]bsent any allegation that [Novo Nordisk] was involved in the claims submission process."[61]

In asserting that Plaintiffs have not sufficiently pleaded causation, Novo Nordisk relies on *Bank of America Corp. v. City of Miami*, which states that proximate causation

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[57] *See U.S. ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 269 (D. Mass. 2009) ("Claims submitted to state Medicaid agencies are considered claims presented to the federal government and may give rise to liability under the FCA.").

[58] *Lemmon*, 614 F.3d at 1172.

[59] Def.'s Mem. (Dkt. 125), at 11 (emphasis added).

[60] *Id.* at 14–15.

[61] *Id.*

"requires a direct relation between the injury asserted and the injurious conduct alleged."[62] Thus, Novo Nordisk concludes, the Supreme Court has "reject[ed] foreseeability as the touchstone of proximate cause analysis."[63] But as Plaintiffs note in their Response, *Bank of America* was a case brought for violations of the Fair Housing Act, not the FCA, and "[p]roximate-cause analysis is controlled by the nature of the statutory cause of action. The question it presents is whether the harm alleged has a sufficiently close connection to the conduct the statute prohibits."[64] Furthermore, courts have consistently applied a traditional proximate-cause test to claims brought under the FCA.[65] It is true that Plaintiffs must allege that Novo Nordisk took "some sort of affirmative action," as opposed to merely alleging that it "passive[ly] acquiesce[d]."[66] But the Second Consolidated Complaint sufficiently describes the underlying alleged fraudulent schemes of off-label marketing and kickbacks,

[62] 137 S. Ct. 1296, 1306 (2017).

[63] Def.'s Mem. (Dkt. 125), at 15–16, n.5.

[64] *Bank of Am. Corp.*, 137 S. Ct. at 1305.

[65] *See Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1107 (11th Cir. 2020) ("[A] defendant's conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct.") (relying on *United States ex rel. Sikkenga v. Regence Bluecross BlueShield of Utah*, 472 F.3d 702, 714–15 (10th Cir. 2006)); *United States v. Luce*, 873 F.3d 999, 1014 (7th Cir. 2017) ("[T]he common-law understanding of foreseeable, or proximate, causation [applies] with respect to the imposition of liability and damages under the FCA."); *United States v. Taneja*, No. 8:21-CV-102-SCB-AEP, 2021 WL 3518206, at *3 (M.D. Fla. Aug. 4, 2021).

[66] *Sikkenga*, 472 F.3d at 714.

which were affirmative acts that could foreseeably lead to the submission of false claims.[67] The Court thus concludes that Plaintiffs have sufficiently pleaded causation under Rule 9(b)'s heighted standard.

Accordingly, Plaintiffs have met Rule 9(b)'s heightened pleading standard with respect to their claim brought under § 3729(a)(1)(A) of the FCA.

b. Count Two

Plaintiffs allege in Count Two that Novo Nordisk violated § 3729(a)(1)(B), which prohibits the use of a false record or statement to demonstrate to the government that a false or fraudulent claim should be paid. As previously mentioned, claims brought under § 3729(a)(1)(B) may not be based upon an implied-certification theory. Thus, to sustain an express-false-certification claim, Plaintiffs must have alleged—with sufficient factual basis—that Novo Nordisk made a false statement and that the statement was material to the government's decision to pay.[68]

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[67] *Cf. United States v. Bewley*, No. 20-CV-39-GKF-JFJ, 2020 WL 12814226, at *3 (N.D. Okla. July 23, 2020) (concluding that the plaintiff sufficiently alleged the defendant "took affirmative acts which caused or assisted the presentation of a fraudulent claim" when the defendant allegedly "recruited and paid physicians to write prescriptions . . . , including prescriptions which were submitted to federal health care programs for reimbursement"); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. CV 02-2964, 2020 WL 6682483, at *358 (E.D. Pa. Nov. 12, 2020) ("In cases where the relator alleges that the defendant *caused* the submission of false claims rather than submitting the claims itself, legal falsity exists when the defendant 'created and pursued a marketing scheme that it knew would, if successful, result in the submission by [others] of compliance certifications . . . that [the defendant] knew would be false.'" (citing *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004)).

[68] *See U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1170 (10th Cir. 2010).

Novo Nordisk argued in its Reply that Plaintiffs' claims are based only upon an implied-false-certification theory.[69] But it has overlooked Plaintiffs' allegations that Novo Nordisk filed with the government express certifications of compliance with applicable federal healthcare-program requirements.[70] Indeed, these allegations of express certifications are accompanied by names, dates, and the certifications' specific language.[71] When viewed alongside Plaintiffs' allegations with respect to Count One, which the Court concludes have met Rule 9(b)'s pleading requirements, Plaintiffs' allegations of specific, express certifications of compliance with federal healthcare-program requirements are also sufficiently pleaded under Rule 9(b).

For the foregoing reasons, Plaintiffs' allegations in the Second Consolidated Complaint based on violations of § 3729(a)(1)(A) and § 3729(a)(1)(B) satisfy Rule 9(b)'s heightened pleading standard for fraud-based claims.

2. Washington State Law Claims (Counts Thirty-One and Thirty-Two)

Plaintiffs have also sufficiently pleaded claims for violations of the Washington Medicaid Fraud False Claims Act ("WFCA") and the Washington Fraudulent Practices Act ("WFPA"). Like the FCA, the WFCA prohibits a person from "[k]nowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" or "[k]nowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement

[69] Def.'s Reply (Dkt. 155), at 3 ("Plaintiffs in this case are proceeding under an implied certification theory of FCA liability.").

[70] *See* Pls.' Resp. (Dkt. 145), at 15 n.20; *see also* Pls.' SCC ¶¶ 197–201.

[71] *Id.*

material to a false or fraudulent claim."[72] And the WFPA makes liable for the repayment of any excess benefits or payments received, plus interest, any person or legal entity that "[o]n behalf of himself or herself or others, obtain[s] or attempt[s] to obtain benefits or payments under this chapter in a greater amount than that to which entitled by means of . . . [a] willful false statement; . . . [a] willful misrepresentation, or by concealment of any material facts; or . . . other fraudulent scheme or device."[73]

Count Thirty-One of the Second Consolidated Complaint alleges that Novo Nordisk violated the WFCA "[b]y virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above."[74] Count Thirty-Two alleges that Novo Nordisk violated the WFPA by virtue of "willful false statements, misrepresentations, concealment of material facts or other fraudulent schemes [that] were made in conjunction with false and fraudulent claims for payment made to the State of Washington."[75] For the reasons explained with respect to Plaintiffs' claims in Counts One and Two based upon alleged violations of the FCA, the Court concludes that Plaintiffs' claims related to alleged violations of the WFCA and WFPA satisfy Rule 9(b)'s heightened pleading standard for fraud-based claims.

3. Various State Law Claims (Counts 3–30, 33–35)

[72] Wash. Rev. Code § 74.66.020.

[73] *Id.* § 74.09.210.

[74] Pls.' SCC ¶ 416.

[75] *Id.* ¶ 422.

In contrast to their claims brought under the FCA and Washington law, Plaintiffs have not sufficiently pleaded Counts Three through Thirty and Counts Thirty-Three through Thirty-Five based upon alleged violations of various state laws. Plaintiffs argue in their Response to Novo Nordisk's Motion to Dismiss that the Second Consolidated Complaint "provides great detail about Novo's nationwide illegal marketing scheme—replete with names, dates, and places."[76] But the Court concludes that, having alleged only one representative example of possible false claims submitted to the government between 2009 and 2013 (namely, Patient A in Washington), Plaintiffs have not "provide[d] an adequate basis for a reasonable inference that false claims were submitted as part of that scheme" in twenty-eight other states, plus the District of Columbia and the City of Chicago, "from at least 2001 to the present."[77] To be sure, Plaintiffs need not allege the "where" of "every single submission of a false claim" to sufficiently allege nationwide fraud.[78] But they must provide more than a single representative example of alleged fraud in one state.[79]

Plaintiffs did allege, however, certain facts with respect to claims in Indiana and off-label promotion at marketing events in several states. But the Indiana example alleges that $46 million was paid on behalf of six Medicare patients who were treated with

[76] Pls.' Resp. (Dkt. 145), at 14.

[77] *Id.*

[78] *See United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 731 (N.D. Ill. 2020).

[79] *Id.* (dismissing state-law claims in twenty-eight states and the District of Columbia because a relator "alleged fraud with particularity in just one state").

NovoSeven "as indicated"[80]—i.e., not for off-label uses—and the discussion of marketing events in several states, unlike the representative Patient A in the State of Washington, does not link any off-label promotion to alleged false claims submitted in those states.[81] Therefore, because the Second Consolidated Complaint pleads with particularity alleged fraudulent claims only in the State of Washington, the Court dismisses without prejudice Counts Three through Thirty and Counts Thirty-Three through Thirty-Five for failure to satisfy Rule 9(b)'s heightened pleading standard.

B. Rule 12(b)(6)

Because the Court finds that the Second Consolidated Complaint fails to satisfy Rule 9(b)'s requirements with respect to alleged false claims submitted outside the State of Washington, this discussion of Rule 12(b)(6) is limited to the surviving Counts: Counts One, Two, Thirty-One, and Thirty-Two. Novo Nordisk maintains that these Counts fail under Rule 12(b)(6) because the Second Consolidated Complaint does not allege facts necessary to state violations under the FCA (Counts One and Two), the WFCA (Count Thirty-One), or the WFPA (Count Thirty-Two). Specifically, it argues that Plaintiffs' allegations about off-label marketing and kickbacks both fail as a matter of law. For the reasons that follow, the Court concludes that Counts One, Two, Thirty-One, and Thirty-Two should not be dismissed for failure to state a claim.

a. Off-Label Marketing

[80] Pls.' SCC ¶ 221.

[81] *Id.* ¶¶ 129–37.

Novo Nordisk argues that Plaintiffs' allegations about off-label marketing of NovoSeven fail to state a claim because (1) they have failed to show that any claim presented to the government was "false"; (2) they have failed to show that Novo Nordisk proximately caused any false claims; and (3) their theory of liability violates the First Amendment. Since the Court has already concluded that Plaintiffs sufficiently alleged causation, the Court will address Novo Nordisk's arguments based on falsity and the First Amendment. The Court rejects both arguments.

Plaintiffs have sufficiently pleaded that the underlying alleged off-label promotion of NovoSeven rendered claims "false" under the FCA. According to Novo Nordisk, Plaintiffs have failed to allege falsity because they have not "allege[d] facts establishing that the off-label prescriptions were not reimbursable."[82] But Plaintiffs have alleged that the off-label uses of NovoSeven—phrophylaxis and dosing regimens above the FDA-approved amount—were not "reasonable and necessary," "medically accepted," or "safe and effective,"[83] which would render these uses ineligible for reimbursement under federal healthcare programs.[84] Specifically, Plaintiffs support their claims with numerous, detailed

[82] Def.'s Mem. (Dkt. 125), at 13.

[83] Pls.' Resp. (Dkt. 145), at 21, 22.

[84] *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018) ("We thus hold that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase.") (citing CMS, *Medicare Program Integrity Manual* § 13.5.1, which provides that an item or service is not "reasonable and necessary" unless it is, among other things, "[s]afe and effective," "[f]urnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition," and "[a]t least as beneficial as an existing and available medically appropriate alternative"). In addition to arguing that Plaintiffs have not

allegations of (1) the dangers of routinely using NovoSeven for off-label phrophylaxis and in high-dose regimens and (2) the greater safety of its competitor's drug, which the FDA had approved for prophylactic use.[85] The Court thus concludes that Plaintiffs' allegations based upon the alleged off-label-promotion scheme do not fail to state a claim.

Novo Nordisk also argues that Plaintiffs' theory of FCA liability based upon off-label promotion "would penalize protected speech based on its content and viewpoint, violating the First Amendment" because "manufacturer promotional speech in other contexts is, at a minimum, entitled to First Amendment protection under the commercial speech doctrine and is not actionable *unless it is false or misleading*."[86] Therefore, "off-label promotion that is false or misleading is not entitled to First Amendment protection."[87] But contrary to Novo Nordisk's assertion, numerous paragraphs in the Second Consolidated Complaint allege that Novo Nordisk's off-label promotion of NovoSeven was indeed false and misleading.[88] To list just a couple of these allegations, Plaintiffs

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shown the claims were non-reimbursable under Medicare and Medicaid, Novo Nordisk argues that Plaintiffs have not shown the claims were non-reimbursable under FEHBP and TRICARE. Novo Nordisk alleges that FEHBP requires off-label uses to be prescribed consistent with medically accepted practices and that TRICARE "generally applies the reimbursement standards applicable to Medicare." *See* Def.'s Mem. (Dkt. 125), at 4. Because the Court finds that Plaintiffs have sufficiently alleged that the off-label uses were neither medically accepted nor reasonable and necessary, the Court's analysis does not distinguish between these government programs in resolving this motion to dismiss.

[85] *See* Pls.' SCC ¶¶ 4, 6, 9, 10, 17, 27, 29, 93–105.

[86] Def.'s Mem. (Dkt. 125), at 16 (emphasis added) (citing *United States v. Caronia*, 703 F.3d 149, 162–68 (2d Cir. 2012)).

[87] *Caronia*, 703 F.3d at 165 n.10.

[88] *See, e.g.*, Pls.' SCC ¶¶ 8–11, 27, 91–92, 94–101, 108, 111–28, 138, 165–68, 175–78, 181–82, 186–96, 202–07, 210–12; *see also* Pls.' Resp. (Dkt. 145), at 27–29.

claim—with specific, factual assertions—that Novo Nordisk's off-label promotion of NovoSeven downplayed the risk of thrombotic events from high-dose and prophylactic use and that Novo Nordisk failed to disclose evidence it gathered that led it to believe that lower doses of NovoSeven were safer and equally effective.[89] Because Plaintiffs have sufficiently pleaded that Novo Nordisk's off-label promotion was false and misleading, the Court rejects Novo Nordisk's argument that Plaintiffs' theory of liability would violate the First Amendment.

Accordingly, Plaintiffs' claims based upon the alleged off-label-promotion scheme do not fail as a matter of law.[90]

b. Kickbacks

For the reasons explained above in relation to Rule 9(b), Plaintiffs have sufficiently pleaded that the underlying alleged kickback scheme rendered claims "false" under the FCA and Washington law. Therefore, Plaintiffs' claims based upon the alleged kickback scheme do not fail as a matter of law.

C. Time-Barred

[89] Pls.' Resp. (Dkt. 145), at 27–28.

[90] As mentioned, Novo Nordisk fails to fully develop any arguments with respect to the FCA's materiality requirement. Novo Nordisk does not argue, for example, that certifications to the government that prescriptions for off-label uses are "reasonable and necessary," when in fact they are not, would not be material to the government's decision to pay a claim. Nevertheless, since the Court concludes that Plaintiffs have sufficiently alleged that the off-label uses were not reasonable and necessary, the Court rejects Novo Nordisk's passing reference to materiality. *See* Def.'s Reply (Dkt. 155), at 4.

Novo Nordisk argues that Plaintiffs' FCA claims should be dismissed to the extent they are time-barred.[91] The FCA provides a ten-year limitations period.[92] Therefore, the Court agrees with Novo Nordisk that any federal FCA claims older than ten years before Plaintiffs filed their original complaint should be dismissed.[93]

D. Additional Reasons to Dismiss or Narrow Claims under Washington Law

Novo Nordisk also argues that Plaintiffs' claims under the WFCA and the WFPA should be dismissed or narrowed for additional reasons. First, Novo Nordisk asserts—and Plaintiffs agree[94]—that the WFCA did not become law until June 2012 and that it does not apply retroactively. Because Plaintiffs make no argument for retroactively applying the WFCA, the Court dismisses their WFCA claims to the extent they are based on conduct that occurred before the WFCA's enactment.

Second, Novo Nordisk argues that the WFCA does not cover kickbacks and off-label promotion. Specifically, it alleges that "no Washington law makes AKS violations or state anti-kickback violations per se violations of the WFCA, and . . . Plaintiffs have not explained how alleged off-label marketing, without more, renders a claim false."[95] The Court disagrees with Novo Nordisk on both counts. As Plaintiffs explain, the WFCA is

[91] The WFCA does not contain a limitations period. Wash. Rev. Code § 74.66.100(2).

[92] 31 U.S.C. § 3731(b)(2).

[93] Dr. Siegel filed her original complaint against Novo Nordisk on February 2, 2015. Pls.' Compl. (Dkt. 1).

[94] Pls.' Resp. (Dkt. 145), at 44 n.45.

[95] Def.'s Mem. (Dkt. 125), at 21.

modeled after its federal counterpart,[96] and numerous courts have looked to federal caselaw to interpret state FCA provisions.[97] Novo Nordisk presents no argument as to why the Court should not look to federal caselaw in interpreting whether off-label marketing and kickbacks would render a claim "false" under the WFCA. Therefore, Plaintiffs' claims based on the WFCA do not fail as a matter of law.

Novo Nordisk also asserts that Plaintiffs' claim under the WFPA should be dismissed or narrowed. It argues (1) that a plain reading of the WFPA shows that it creates an administrative enforcement scheme, not a cause of action; (2) that the amendments to the WFPA are not retroactive; and (3) that the WFPA applies only to "provider[s] who submitted claims." The Court rejects each argument.

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[96] *See United States ex rel. Dahlstrom v. Sauk-Suiattle Indian Tribe of Washington*, No. C16-0052JLR, 2019 WL 4082944, at *14 (W.D. Wash. Aug. 29, 2019).

[97] *See, e.g.*, *State v. Alius Fin. S.A.*, 32 Cal. Rptr. 3d 498, 116 P.3d 1175, 1184 (Cal. 2005) (California); *Payne v. District of Columbia*, 773 F. Supp. 2d 89, 97 n.4 (D.D.C. 2011) (District of Columbia); *United States ex rel. Heater v. Holy Cross Hosp., Inc.*, 510 F. Supp. 2d 1027, 1033 n.5 (S.D. Fla. 2007) (Florida); *Cade v. Progressive Cmty. Healthcare, Inc.*, No. 1:09-cv-3522-WSD, 2011 WL 2837648, at *3 (N.D. Ga. July 14, 2011) (Georgia); *United States ex rel. Woodruff v. Haw. Pac. Health*, 560 F. Supp. 2d 988, 997 n.7 (D. Haw. 2008) (Hawaii); *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916 n.1 (8th Cir. 2014) (Iowa); *United States ex rel. Humphrey v. Franklin-Williamson Human Servs., Inc.*, 189 F. Supp. 2d 862, 867 (S.D. Ill. 2002) (Illinois); *Thomas v. EmCare, Inc.*, No. 4:14-cv-00130-SEB, 2015 WL 5022284, at *2 n.2 (S.D. Ind. Aug. 24, 2015) (Indiana); *Scannell v. Att'y Gen.*, 70 Mass.App.Ct. 46, 872 N.E.2d 1136, 1138 n.4 (Mass. App. Ct. 2007) (Massachusetts); *United States v. Bon Secours Cottage Health Servs.*, 665 F. Supp. 2d 782, 783 n.2 (E.D. Mich. 2008) (Michigan); *New York v. Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011) (New Mexico); *United States ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 816 (S.D.N.Y. 2010) (New York); *United States v. Planned Parenthood*, 21 F. Supp. 3d 825, 831 n.24 (S.D. Tex. 2014) (Texas); *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 305 (S.D.N.Y. 2013) (New York).

First, the 2012 amendment to the WFPA shows that the statute creates more than a narrow administrative remedy. The amendment authorized the State Attorney General to enforce the WFPA and assess civil penalties.[98] Furthermore, the amendment added the "director" of the state's Medicaid program agency—but not the "attorney general"—to the section providing a defendant with right to notice and an "adjudicative hearing" when a fine is assessed.[99] The Washington legislature also gave the Attorney General authority to hire private attorneys "in bringing actions" under the WFPA,[100] and it clarified in the 2012 amendment that the Washington Administrative Procedures Act[101] applies only to *administrative* proceedings under the WFPA.[102] Therefore, the Court is unpersuaded by Novo Nordisk's argument that the State of Washington may not enforce the WFPA against Novo Nordisk in the context of this lawsuit.

Second, the Court agrees with Plaintiffs that the 2012 amendment to the WFPA, which authorized the Attorney General to bring actions under the statute, apply retroactively. As Plaintiffs note, while legislative enactments generally apply only

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[98] Wash. Rev. Code § 74.09.210(2).

[99] *Id.*

[100] *Id.* § 74.09.210(6).

[101] *Id.* § 34.05.

[102] *Id.* § 74.09.210(4) ("In all administrative proceedings under this section, service, adjudicative proceedings, and judicial review of such determinations shall be in accordance with chapter 34.05 RCW, the administrative procedure act."). *See Perez-Crisantos v. State Farm Fire & Cas. Co.*, 187 Wash. 2d 669, 680, 389 P.3d 476, 481 (2017) ("[W]here a statute specifically designates the things upon which it operates, there is an inference that the Legislature intended all omissions. And where the legislature includes particular language in one section of a statute but omits it in another, the exclusion is presumed intentional." (cleaned up)).

prospectively, an amendment to an existing statute will be applied retroactively if it is "remedial and its remedial purpose is furthered by retroactive application," in which case "the presumption favoring prospective application is reversed."[103] "A remedial statute is one which relates to practice, procedures and remedies and is applied retroactively when it does not affect a substantive or vested right."[104] Novo Nordisk does not argue that retroactively applying the 2012 amendment affects any substantive or vested right, nor does it address Plaintiffs' argument that the 2012 amendment is remedial and that its retroactive application would further a remedial purpose. Therefore, the Court rejects Novo Nordisk's argument that the 2012 amendment should not be applied retroactively.

And third, the Court agrees with Plaintiffs that the WFPA's plain text shows that it applies to Novo Nordisk's alleged fraudulent claims. The WFPA provides, in relevant part, that

> [n]o person, firm, corporation . . . or other legal entity . . . shall, *on behalf of himself or herself or others*, obtain or attempt to obtain . . . payments . . . in a greater amount than that to which entitled by means of:
>
> (a) A willful false statement;
>
> (b) By willful misrepresentation, or by concealment of any material facts; or
>
> (c) By *other* fraudulent scheme or device.[105]

Novo Nordisk argues that it, as a "secondary actor," did not make statements or submit claims for payment and that the WFPA says nothing of the liability of "others." But the

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[103] *Haddenham v. State*, 87 Wash. 2d 145, 148, 550 P.2d 9, 12 (1976).

[104] *State v. McClendon*, 131 Wash. 2d 853, 861, 935 P.2d 1334, 1339 (1997).

[105] Wash. Rev. Code § 74.09.210(1) (emphasis added).

Second Consolidated Complaint alleges that *Novo Nordisk*—on behalf of itself and others, not as a secondary actor—made false and misleading statements, concealed material facts, and committed "other fraudulent scheme[s] and device[s]" through its alleged off-label marketing and kickbacks. The Court thus concludes that Plaintiffs' WFPA claim does not fail as a matter of law.

E. Motion to Dismiss the Second Consolidated Complaint in Part Pursuant to Anti-SLAPP Statutes

Novo Nordisk also requests that the Court dismiss certain counts in the Second Consolidate Complaint pursuant to various states' Anti-SLAPP statutes. Specifically, Novo Nordisk asks the Court to dismiss Counts Three, Four, Eight, Nine, Eleven, Twelve, Fourteen, Fifteen, Sixteen, Twenty, Twenty-Six, Twenty-Seven, Twenty-Nine, Thirty-Four, and Thirty-Five. Because the Court has already dismissed these counts for failure to satisfy Rule 9(b)'s heightened pleading standard, Novo Nordisk's Motion to Dismiss the Second Consolidated Complaint in Part Pursuant to Anti-SLAPP Statutes (Dkt. 127) is **DENIED AS MOOT**.

Conclusion

For the foregoing reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Novo Nordisk's Motion to Dismiss the Second Consolidated Complaint (Dkt. 124) and **DENIES AS MOOT** its Motion to Dismiss the Second Consolidated Complaint in Part Pursuant to Anti-SLAPP Statutes (Dkt. 127). The Court finds that Plaintiffs have met Rule 9(b)'s heightened pleading standard for Counts One, Two, Thirty-One, and Thirty-Two, but not for the remaining counts in the Second Consolidated Complaint. Accordingly, the

Court dismisses without prejudice Counts Three through Thirty and Counts Thirty-Three through Thirty-Five. The Court also finds that Counts One, Two, Thirty-One, and Thirty-Two do not fail as a matter of law. These four Counts, however, are dismissed to the extent they are time-barred, as explained above.

IT IS SO ORDERED this 4th day of November 2022.

PATRICK R. WYRICK
UNITED STATES DISTRICT JUDGE